NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT TO ADMINISTRATIVE REGULATION

A public hearing will be conducted at 9:00 a.m., on the 24th day of September, 2008, at the Topeka & Shawnee County Public Library, 1515 SW 10th Avenue, Room 101B, Topeka, Kansas 66604, to consider the amendment of K.A.R. 68-7-12b of the Kansas Pharmacy Board.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed amendment of K.A.R. 68-7-12b. All parties may submit written comments prior to the hearing to the Executive Secretary of the Kansas Pharmacy Board, Debra Billingsley, pharmacy.ks.gov or Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231. All interested parties will be given a reasonable opportunity to present their views orally on the amendment of the regulation during the hearing. In order to give all parties an opportunity to present their views, it may be necessary to request each participant to limit any oral presentation to five minutes.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the regulation and economic impact statement in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting the Kansas Pharmacy Board, Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231, (785) 296-4056. Handicapped parking is located on the west and north sides of the building, and the north entrance to the building is accessible to individuals with disabilities.

The regulation is proposed for amendment. A summary of the proposed regulation is as follows:

K.A.R. 68-7-12b. Incident reports. This regulation identifies the information that shall be included in an incident report when a pharmacist becomes aware of a reportable incident. The regulation also specifies what constitutes a reportable incident and the recordkeeping

requirements regarding an incident report.

Copies of the regulation and the economic impact statement may be obtained from the Kansas Pharmacy Board, Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231, (785) 296-4056, or by accessing the Board's website at http://www.accesskansas.org/pharmacy/leg.html.

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ECONOMIC IMPACT STATEMENT

Pursuant to K.S.A. 77-420(b), the Kansas Pharmacy Board submits the following description of the economic impact of K.A.R. 68-7-12b.

- 1. This regulation already identifies that procedures shall exist at each pharmacy other than a medical care pharmacy regarding the preparation of an incident report. The regulation also identifies various recordkeeping requirements for an incident report. New provisions are now proposed to delineate what constitutes a "reportable incident" and "incident" for purposes of preparing an incident report.
- 2. The proposed regulation is not mandated by federal laws.
- 3. No new costs will be borne by pharmacists, pharmacy technicians, or others.
- 4. The Board is not aware of any less costly or less intrusive methods to achieve the stated purpose and thus none were considered.
- 5. This is not a proposed environmental regulation.

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68-7-12b. Incident reports. (a) For purposes of this regulation, "reportable incident" and "incident" shall mean a preventable medication error involving a prescription drug and resulting in any of the following:

- (1) The patient receiving the wrong drug;
- (2) the patient receiving an incorrect drug strength;
- (3) the patient receiving an incorrect dosage form;
- (4) the drug being received by the wrong patient;
- (5) inadequate or incorrect packaging, labeling, or directions; or
- (6) the dispensing of a drug to a patient in a situation that results in or has the potential to result in serious harm to the patient.
- (b) For each pharmacy other than a medical care pharmacy, the pharmacist-in-charge shall ensure that procedures exist requiring each pharmacist who becomes aware of an alleged or real error in filling or dispensing a prescription a reportable incident to report the incident to the pharmacist-in-charge as soon as practical.
- (b) (c) As soon as possible after discovery of the incident, the pharmacist shall prepare a report containing the following information:
- (1) The name, address, age, and phone number of any complainant, if available;
- (2) the name of each pharmacy employee and the license number of each licensee involved:

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(3) the date of the incident and the date of the report:

(4) a the pharmacist's description of the incident;

(5) the prescriber's name and whether or not the prescriber was contacted;

<u>and</u>

(6) a description of the actions taken as a result of the incident;

(7) the steps taken to prevent a recurrence; and

(8) the signatures of all pharmacy employees involved in the incident.

For each pharmacy, the pharmacist-in-charge shall ensure that procedures exist requiring that the incident report be maintained in the pharmacy for at least five years in a manner so that the report can be provided to the board or its representative immediately within three business days, upon request.

(e) (d) The preparation of an incident report that meets the requirements of this regulation shall be the responsibility of each pharmacist involved in the incident and the pharmacist-in-charge. The maintenance of incident reports as required by this regulation shall be the responsibility of the pharmacist-in-charge. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2007 Supp. 65-1626d; effective Feb. 7, 2003; amended P-_______.)

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(Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 2007 Supp. 65-1626(t), as amended by L. 2002, ch. 25, sec.2 and K.S.A. 2007 Supp. 65-1626d; effective Feb. 7, 2003; amended P-

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